dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

Claim 11 relates to a chewable tablet comprising such taste masked particles.

Claim 19 recites a method of taste masking particles comprising an active ingredient, which comprises applying a continuous polymeric coating over said particles, said coating comprising a mixture of a) an enteric polymer; and b) a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

The Examiner has rejected claims 1, 6, 9, 11, 16, 18, 19, and 24 under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner argues the term "insoluble film forming polymer" is unclear insofar as it does not state what it is insoluble in. Although applicants believe the term is clear, and would be readily understood by one skilled in the art, the phrase has been changed to "water insoluble film forming polymer," as suggested by the Examiner. No new matter is added by this amendment, support for which is contained in the specification on page 4, line 30 to page 5, line 2.

Claims 1-25 have been rejected under 35 U.S.C. §102(b) as anticipated by Canadian Application No. 2,068,366. The Examiner argues this reference discloses a taste masked, free flowing powder including microcapsules, in which each microcapsule includes a core including an active ingredient, and a substantially smooth and continuous microcapsule coating that contains a water insoluble polymer and may also include an enteric polymer. The Examiner maintains that all of the features of applicants' other claims are also disclosed.

Applicants disagree. Canadian Application No. 2,068,366 describes a microcapsule composition and process for making the same. The dissolution profile of the microcapsule is reduced by approximately 25%, preferably approximately 40%, more preferably approximately 50%, relative to a standard microencapsulated tablet when measured at a pH of about 6.8. The coating solution of the Canadian Application contains 3 to 75 wt % of a water insoluble polymer. The coating solution may optionally contain an enteric, reverse enteric, or water soluble polymer as well.

The Canadian Application does not teach or suggest combinations of enteric polymers and water insoluble film forming polymers to obtain immediate release-type dissolution profiles. This is an aim of the present invention. See page 7, lines 16-25 of the specification.

Instead, Example 3 of the Canadian Application, in which an enteric coating comprising ethylcellulose, hydroxypropyl methylcellulose acetate succinate and dicloromethane was spray dried with sodium diclofenac showed "a typical enteric release profile." Canadian Application, page 19, lines 19-20. The release profile of the enteric coated diclofenac, shown in Figure 3, indicates that less than 80 % of the drug had been released after 30 minutes in a pH 7.5 solution.

In contrast, the independent claims herein now recite that the active ingredient is at least 80% dissolved in 30 8minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm. This is neither taught nor suggested by the Canadian Application.

For these reasons, applicants submit the claims are patentable.

Respectfully submitted,

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AMENDED CLAIMS SHOWING CHANGES

1. (amended) A taste masked particle comprising a core containing an active ingredient and a continuous polymeric coating covering said core, said coating comprising a mixture of a) an enteric polymer; and b) ~~an~~ a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

6. (amended) The particle of claim 1, wherein the water insoluble film forming polymer is selected from the group consisting of cellulose acetate and ethylcellulose.

9. (amended) The particle of claim 1 wherein the weight ratio of enteric polymer to water insoluble film forming polymer in the coating is in the range of about 20:80 to about 80:20.

11. (amended) A chewable tablet comprising taste masked particles, each particle comprising a core containing an active ingredient and a continuous polymeric coating covering said core, said coating comprising a mixture of a) an enteric polymer; and b) ~~an~~ a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

16. (amended) The chewable tablet of claim 11, wherein the water insoluble film forming polymer is selected from the group consisting of cellulose acetate and ethylcellulose.

18. (amended) The chewable tablet of claim 11, wherein the weight ratio of enteric polymer to water insoluble film forming polymer in the coating is in the range of about 20:80 to about 80:20.

19. (amended) A method of taste masking particles comprising an active ingredient, which comprises applying a continuous polymeric coating over said particles, said coating comprising a mixture of a) an enteric polymer; and b) ~~an~~ a water insoluble film forming polymer, wherein the active ingredient is at least 80% dissolved in 30 minutes in pH 7.2 phosphate buffer when tested according to USP method II at 50 rpm and is at least 70% dissolved in 60 minutes in pH 5.6 acetate buffer when tested according to USP method II at 50 rpm.

24. (amended) The method of claim 19, wherein the water insoluble film forming polymer is selected from the group consisting of cellulose acetate and ethylcellulose.